California's Stem Cell Agency Applauds FDA for Crackdown on Stem Cell Clinics that "Peddle Unapproved Treatments."

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Oakland, CA – The California Institute for Regenerative Medicine (CIRM), the state's Stem Cell Agency, commends the US Food and Drug Administration (FDA) for its action against two stem cell clinics offering unapproved therapies.

Yesterday, the FDA filed two complaints in federal court seeking a permanent injunction against California Stem Cell Treatment Center Inc. and US Stem Cell Clinic LLC of Sunrise, Florida. The FDA says the clinics are marketing stem cell products without FDA approval and are not complying with current good manufacturing practice requirements.

"We strongly support the FDA's strong stance to seek judicial action to stop these clinics from marketing unproven therapies that pose a threat to the safety of patients" says Maria T. Millan, M.D., CIRM's President and CEO, and "we agree with FDA Commissioner Dr. Scott Gottlieb's statement that these 'bad actors leverage the scientific promise of this field to peddle unapproved treatments that put patients' health at risk.'"

In his statement yesterday, Dr. Gottlieb denounced the clinics saying they are exploiting patients and causing some of them "serious and permanent harm."

"In the two cases filed today, the clinics and their leadership have continued to disregard the law and more importantly, patient safety. We cannot allow unproven products that exploit the hope of patients and their loved ones. We support sound, scientific research and regulation of cell-based regenerative medicine, and the FDA has advanced a comprehensive policy framework to promote the approval of regenerative medicine products. But at the same time, the FDA will continue to take enforcement actions against clinics that abuse the trust of patients and endanger their health."

CIRM believes it is critically important for participants in stem cell treatments to be fully informed about the nature of the therapy they are receiving, including whether it is approved by the FDA. Last year CIRM partnered with California State Senator Ed Hernandez to pass Senate Bill No. 512, which required all clinics offering unproven stem cell therapies to post notices warning patients they were getting a therapy that was not approved by the FDA.

The Stem Cell Agency has taken several other actions to protect people seeking legitimate stem cell therapies.

- All the clinical trials we consider for funding must already have an active Investigational New Drug (IND) status with the FDA and go through a rigorous scientific review by leading experts.
- All CIRM-funded trials must adhere to strict regulatory standards and safety monitoring.
- We have created the CIRM Alpha Stem Cell Clinics, a network of six top California medical centers that specialize in delivering patient-centered stem cell clinical trials that meet the highest standards of care and research.
- CIRM provides access to information on all the clinical trials it supports.

"Through its funding mechanism, active partnership and infrastructure programs, CIRM has shepherded 48 FDA regulated, scientifically sound, rigorously reviewed promising stem cell and regenerative medicine projects into clinical trials," says Dr. Millan. "Some of these treatment protocols have already started to show preliminary signs of benefit for debilitating and life-threatening disorders. We are committed to doing all we can, in partnership with patients, the research community and with the FDA, to develop transformative treatments for patients with unmet medical needs while adhering to the highest standards to protect the health and safety of patients and the public."

To help people make informed decisions CIRM has created an infographic and video that detail the information people need to know, and the questions they should ask, before they agree to participate in a clinical trial or get a stem cell therapy.

About CIRM

At CIRM, we never forget that we were created by the people of California to accelerate stem cell treatments to patients with unmet medical needs, and act with a sense of urgency to succeed in that mission.

To meet this challenge, our team of highly trained and experienced professionals actively partners with both academia and industry in a hands-on, entrepreneurial environment to fast track the development of today's most promising stem cell technologies.

With $3 billion in funding and approximately 300 active stem cell programs in our portfolio, CIRM is the world's largest institution dedicated to helping people by bringing the future of cellular medicine closer to reality.

For more information go to www.cirm.ca.gov

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